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(COMPLIANCE AUDIT PROGRAM)

11812

# TSCA CONFIDENTIAL BUSINESS INFORMATION

ORIGINAL - TDAS (BLAKE)

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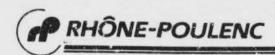
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NOTE: Peter provides data entry in CBITS for the 8(e) CAP Documents.

# Contains No CBI



RHÔNE-POULENC INC.

CN 7500, CRANBURY, NJ 08612-7500 TELEPHONE (609) 395-8300

October 27, 1992

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 416 555 462

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460





RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO .: RPS - 0400

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Chemical Identity:

Fluosilicic acid

CAS Registry No.:

16961-83-4

CAS Registry Name:

Hydrogen hexafluorosilicate

The title of the enclosed report is:

Toxicology Lab Report T-1731

The following is a summary of the adverse effects observed in this report.

The oral LD50 was 430 mg/kg and thus, the compound would be classified as moderately toxic based on EPA's criteria under Section 8(e). Fluosilicic acid was also found to be corrosive to the skin and eyes of rabbits. In the skin irritation test, severe erythema and edema were observed. No evidence of reversibility was seen in either the skin or eye irritation studies. The exact pH of this chemical is not known, but the Merc!. Index indicates that the chemical is a fairly strong acid. The irritation results for phosphoric acid are not considered to meet the reporting criteria of Section 8(e) as this chemical has a pH of less than 1.0.

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.

Oula & Mynh

Director, Product Safety

(609)860-3589

CEMjr/nim Enclosures

# BEGIN REPORT

REVIEWED FOR THE SECTION 8(e) COMPLIANCE

AUDIT FROGRAM, ON 3-2-92 BY

1015 CAD ID NO 18-08-125

# TOXICOLOGY REQUEST FORM

	T-No. 1731
	Project No. 70-0410
Compound WET PHOS PHOR; C A  Compound WET PHOR;	
Jse (insect., herbicide, etc.)	VARIOUS
STRUCTURE	Purity (%) 70 by (IR, m.p.,etc) Known Impurities
Complete for formulations:  Per cent technical solvent per cent	
Check and Complete:	
Acute oral toxicity - species  Acute dermal toxicity - rabbit  Primary skin irritation (Indus  Acute eye irritation - rabbits	ts strials) - rabbits
Other (specify)	
Report Distribution NOR~AL + SA	LT LAKE PLANT PERSONNE
Remarks	
	Bu Cara Java City Olar

Requested By SALT LAKE CITY, PLANT

#### STAUFFER CHEMICAL COMPANY

#### WESTERN RESEARCH CENTER

#### COMPANY CONFIDENTIAL

#### TOXICOLOGY LAB REPORT T-1731

July 21, 1971

#### FLUOSILICIC ACID AND WET PHOSPHORIC ACID 0-70-0

#### I. OBJECTIVE

- 1. To evaluate the acute oral toxicity and the skin and eye irritation properties of FLUOSILICIC ACID.
- 2. To evaluate the skin and eye irritation properties of wet phosphoric acid.

#### II. MATERIALS

- 1. FLUOSILICIC ACID. 23% approx. received from the 1415 South 47th Street, Richmond Plant on April 22, 1971.
- Wet PHOSPHORIC ACID 0-70-0. Received from the Salt Lake City Plant May 12, 1971.

#### III. SUMMARY

		FLUOSILICIC	PHOSPHORIC
1.	Skin irritation index and classification	8.0* corrosive	8.0** corrosive
2.	Eye irritation classification	corrosive	corrosive
3.	Acute oral LD <sub>50</sub> , female rats, mg/kg	430 (295-626)	

\*A modified Draize dermal of one hour exposure indicated the material is primary irritant.

\*\*Because of perforations of the abdominal walls of all test rabbits, observations were made 24 hours after treatment. A one hour exposure also indicated the material was corrosive.

#### IV. PROCEDURES

#### A. Skin Irritation Index. Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evalutaing hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and ve. sulation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

#### B. Acute Eye Irritation

The procedure employed is in accordance with the test for eye irritants outlined in the Code of Federal Regulations (Part 191.12, Chap. 1, Title 21) for evaluating hazardous substances.

Six New Zealand rabbits in the 1.6-2.1 kg weight range were used as the test animals. Ten mg or 0.1 ml of the test material was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test material is dropped. The lids were gently held together for one second and the animal released. The other eye, remaining untreated, served as the control. The eyes were observed at 24, 48 and 72 hours following treatment and scored for irritation properties.

Eye irritation was determined according to the method outlined in the "Illustrated Guide for Grading Eye Irritation by Hazardous Substances." A total score of 110 is possible. A non-irritant must have a score of 10 or less. If, at the end of 72 hours ocular damage appears to be remissible (reversible), the animal is observed for an additional 4-7 days before final scoring is possible.

#### C. Acute Rat Oral

Sprague Dawley albino white rats in the 200 gram weight range were used in the study. The material was administered in water in single doses to fasted rats by means of a stomach tube. Five animals were used for each dose level. Test animals were fasted for 24 hours prior to treatment. The animals were observed 14 days for mortalities and signs of toxicity. The mortalities and survivors of the highest test level were autopsied for gross pathological observation after the 14 day period.

#### V. PESULTS

A. Skin Irritation, Draize Dermals

See charts on page 4.

- B. Eye Irritation, Rabbits
- FLUOSILICIC ACID -- produced severe and permanent corneal opacity with scar tissue.
- WET PHOSPHORIC ACID -- produced total descruction of the entire eye structure and all surrounding tissues.
  - C. Acute Oral, Female Rats

# FLUOSILICIC ACID

1. Mortality: Dose Level, mg/kg

215 464 1,000 2,150

0/5 3/5 5/5 5/5

#### 2. Signs of Toxicity:

No apparent signs of toxicity were observed at the 215 mg/kg dose level. Higher dose levels produced acute depression.

#### 3. Gross Pathology

The animals of the 215 mg/kg dose level appeared grossly normal when necropsied 14 days after treatment. Mortalities exhibited massive areas of hemorrhage of the entire gastrointestinal tract.

Work done by: A. Hall

J. Saylor

C. Bullock

Submitted by C. X. Bullock

C. H. Bullock

Approved by F. X. Kamienski

FXK:ea

-

expos.		4M	5M	- 6M	20F	23F	24F	
ime Hrs.	ERYTHEMA	Score	Score	Score	Score			Means
24	Intact	4	4	4	4	4	4	4
72	Intact	4	4	4	4	4	4	4
24	Abraded	4	4	4	4	4	4	4
72	Abraded	4	-4	4	4	4	4	4
						SUBTO	TAL	16
	ELEMA							
24	Intact	4	4	4	4	4	4	4
72	Intact	4	4	4	4	4	4	4
24	Abraded	4	4	4	4	4	4	4
72	Abraded	4	4	4	4	4	4	4
						SUBTO	TAL	16
					TO	TAL SC	ORE	32
		(!	TAL ,	/4) PR	IM. IR	T. IN	DEX	8

#### 2. PHOSPHORIC ACID

# RABBIT NO.

HORIC ACID	1.7M	19M	LCVDDT.		1 36F	100	
ERYTHEMA	The second second	The second second	- The second second	THE RESERVE AND ADDRESS OF THE PERSON NAMED IN	A STATE OF THE PARTY OF THE PAR		Mean
Intact	4	4	4	4	4	4	4
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Abraded	4	4	4	4	4	4	4
Abraded							4
					SUBTO	TAL	16
EDENA							
Intact	4	4	4	4	4	4	4
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#### APPENDIX A

#### DESCRIPTION OF THE DRAIZE DERMAL SKIN IRRITATION TEST

The Draize dermal method of testing primary irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduce under a square patch such as surgical gauze measuring 1 inch x 1 inch, two single layers thick, 0.5 milliliter (in case of liquids) or 0.5 gram (in the case of solids and semisolids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material such as rubberized cloth for the 24-hour period of exposure. This material aids in maintaining the test patches in position and retards the evaporation of volatile substances. After 24 hours of exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following table:

mateu values in the following table.	
Evaluation of skin reactions Value  Erythems and eschar formation:	ie i
No erythems	0
Very slight crythema (barely percep- tible)	1
Well-defined erythema	
	3
Moderate to severe erythema	3
Severe erythema (beet redness) to	
alight eschar formation (injuries in	-
depth)	*
Edema formation:	
No edema	0
Very slight edema (barely perceptible) -	1
Slight edems (edges of area well de-	
fined by definite raising)	2
Moderate edema (raised approximately	-
1 millimeter)	3
Severe edema (raised more than 1	
millimeter and extending beyond the	
area of exposure)	•

The "value" recorded for each reading is the average value of the six or more animals subject to the test. Readings are again made at the end of a total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this parag.aph. Add the values for erythema and Eschar formation at 24 hours and at 72 hours for intact sky to the values on abraded skin at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score. Example:

	Exposure time	Exposure
Erythems and eschar formation: Intact skin Do Abraded skin Do	Hours 24 72 24 77	Value
Edema formation: Intact skin	24 12 24 72	0
Eabtotal		
Total		r

Primary irritation .core is 12+4=3.

Compounds producing combined averages (primary irritation indexes) of 2 or less are only mildly irritating; whereas those with indexes from 2 to are moderate irritants, and those with scores above are considered severe or primary irritants.

## MODIFIED

CONFIDENTIAL

DERMAL	TOXICITY	RABBIT
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Operator JS, AH,	CB Star	rting Date	-15-76	T	No. 7-173/-/
Compound Wet Pa	rosphore	Mary U	cid -	70%	
Concentration	AS RECEIVE	D (NEA	7)	Do	sage O. Scc or.
Solvent Liquins	NEAT / SOLIE	S MOISTEN	Ed WITH	Ha O PH	PER PATCH
Experimental Des	ign_/2/.//	modified	FOR 1	HOUR	EXPOSURES,
PERFORMED	ON SAM	E ANIM	L AS	24	HOUR EXPOSU

					_		RABBIT	NO.		.0	
Rab.	Body	Time	Expos. Time Hrs.	EDVTUENA	50000	Score	Score	35	36	17	Manna
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			73	Abraded							
									SUBTO	TAL	
					R			TO	TAL SC	ORE	
					(	TOTAL /	/6) PR	M. IR	IT. IN	DEX	
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THIS TEST IS DESIGNED TO DETERMINE

SHORT EXPOSURE CORRESIVE QUALITYS. DOES

NOT NECESS ARILY CORRELATE WITH DRAIZE

INDEX. (Abdominal cavities of all animals were

perpetus after 24 hours exposure. Assimals were

Cavities after 24 hours exposure. Assimals were

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T-1731-2 4500(295-626)

Stauffer Chemical Compan Western Research Center Toxicology Section

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Material A luos lecis	- avid	Batch #	
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Factor 1.08			
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1.07			

T-1731-2

Stauffer Chemical Compar Western Research Center Toxicology Section

ACUTE ORAL SHEET &

.Date 6-16-71	CONFIDENTIAL	
Material Fluosilinia Mail	CONFIDENTIAL  Batch #	
Dose 464 my! Kg		
Concentration 200 mod [ml -	20 7: (	H20
Factor 2.32		
Rat No. ( Body Weight (g)	Total Dose (ml)	71 24
2 210	0.49	~
3 200 -	0.46	
4 (6)	0,57	12
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Observations:		
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# T-1731-2

Stauffer Chemical Company Western Research Center Toxicology Section

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Material Fluosilicio	- acid	Pato	:h #	
Dose 1000 mg/ tg				
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DERMAL TOXICITY RAGGIT

Operator JS, AH, CB Starting pate 6-13-7/ T No. T-1731-2

Compound Hoursilicic Acid

Concentration AS RECEIVED (NEAT) Dosage 0.5 CC OR.5

Solvent Liquids NEAT / Solids moistened with Had PH —

Experimental Design 121.11 modified FOR 1 Hours Exposures,

PERFORMED ON SAME ANIMAL AS QUI HOUR EXPOSUR

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67	1900	13	25	Abraded	44	44	44	44	44	44	74			
204	2000	150	73	Abraded	4	4	4	4	4	4	4			
234	2300	19							SUBTO	TAL	19			
24	2400 Term	15	24/25	Intact	73	2/2	0%	0/	1/2	1/2	1.33			
	Wt.Kq.		79	Intact	3	2	0	0	2	3	1.66			
			× /25	Abraded	2/3	23	2/3	2/	1/3	3/2	22.33			
			73	Abraded	3	3	2	1	3	2	2.33			
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					(	TOTAL /	(6) PR	M. IR	T. IN	DEX ,	5.16			

THIS TEST IS designed TO determine
SHORT EXPOSURE CORROSIUE QUALITYS. DOES
NOT NECESSARILY CORRELATE WITH DRAIZE
JNDEX.

SUBTOTAL

TOTAL SCORE

(TOTAL /4) PRIM. IRIT. INDEX

Corrosiu

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EYE TO	XICITY Pallet T NO. T-1731-2
	g pate 6-15-7/ Rabbit No
compound Filesolinia Ocio	
Concentration As reco	Dosage Oil-ml
Solvent Mane	PH
Experimental Design Ollow invi	illed in left eye.

	Date	Body Wt.Ka	Time Dosed	Time Obs.Hr.	Co	nea	Score	Iri Irit	s Score	Con	unc Ed.	tiva Dis.	e Isc.	Tot. Score
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